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[A RATE ADAPTIVE PACEMAKER
Technical Field]

SPECIFICATION

TITLE

"A RATE ADAPTIVE PACEMAKER"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a rate adaptive pacemaker [comprising a means] of the type having an arrangement for determining the demand of the patient's organism, a pacing rate [controlling means] control for controlling the pacing rate in response to the patient's demand, and a pacing rate [limiting means] limiter for preventing the pacing rate from becoming too low.

[Background Art]

Description of the Prior Art

The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is [previously] known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus [US-A-] United States Patent No. 4,535,774 describes a stroke volume controlled

pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in [US-A-] United States Patent No. 5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night time setting of a lower rate limit to [a] the lower value than the pacemaker daytime setting of the lower rate limit. In [US-A-] United States Patent No. 5,183,040, an antitachycardia pacer is disclosed which analyzes cardiac output information for assessing hemodynamic status and determining adequate blood supply.

Thus, [too low] a pacing rate that is too low may cause [too slow] an influx of blood enriched with oxygen that also is too low. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough so as to not to disturb a peaceful sleep. In that case the patient can feel more healthy in various everyday life conditions including peaceful sleeping.

SUMMARY OF THE INVENTION

[The purpose] An object of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented [in a new way] from becoming too low, such that the above discussed inconveniences for the patient are avoided.

[Disclosure of the Invention

This purpose is obtained by a rate adaptive pacemaker according to claim 1.]

The above object is achieved in accordance with the principles of the present invention in a rate adaptive pacemaker having an arrangement adapted for interaction with a subject for obtaining an electrical signal representing cardiac demand of the subject, a computing unit supplied with the signal for calculating an actual cardiac output CO and a cardiac output CO_{rest} for the subject at rest, a pacing rate controller also supplied with the signal for generating, as an output, a pacing rate dependent on the cardiac demand, and a pacing rate limiter connected to the computing unit and to the pacing rate controller for downwardly limiting the pacing rate, wherein the pacing rate limiter calculates a stroke volume SV and a stroke volume SV_{rest} for the subject at rest, and downwardly limits the pacing rate so that a first predetermined relation $CO > CO_{rest}$ and a second predetermined relation $SV/SV_{rest} < L$ are satisfied, wherein L is a predetermined constant in a range between 1.2 and 1.5.

Thus, by satisfying two predetermined relations the pacemaker according to the invention ensures a sufficient minimum energy supply to the patient's organism or body and at the same time the maximum value of the stroke volume is limited and these conditions are continuously automatically checked.

[Preferred embodiments are set forth in the dependent claims.]

[According to an advantageous] In one embodiment of the pacemaker 20 according to the invention the first predetermined relation

is

$$CO > CO_{rest} \quad (1)$$

and [said] the second predetermined relation is

$$(SV)/(SV_{rest}) < L \quad (2)$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5. In this way it is ensured that the actual cardiac output [is ensured] will not [to] become lower than the rest state cardiac output CO_{rest} [and] as well as ensuring that the actual stroke volume [is ensured to] will be less than a maximum allowed value equal to L x SV_{rest}, where L typically has a value between 1.2 and 1.5, depending on the health of the patient's myocardium. By satisfying both these conditions simultaneously a physiologically well founded heart work management at low work loads is ensured.

[According to other advantageous embodiments] In another embodiment of the pacemaker according to the invention the pacing rate [limiting means] limiter includes a lower limit setting [means] unit for setting a lower limit value for the pacing rate, and a lower limit determining [means] unit for determining the relation between actual cardiac output (CO) and cardiac output (CO_{rest}) for the patent in rest conditions, and the relation between actual stroke volume (SV) and a rest stroke volume (SV_{rent}) and for calculating a lower pacing rate limit value from [said] the relations for supply to said limit setting [means, and said] unit. The lower limit determining [means] unit includes a stroke volume measuring [means] unit for measuring actual stroke volume SV and [comparison means] a comparator for

comparing measured actual stroke volume SV with stroke volume SV_{rest} for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L \quad (3)$$

is satisfied [and said]. The lower limit determining [means] unit is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} (_{Svrest}/SV) \quad (4)$$

where HR_{rest} denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate HR_{rest} for rest conditions of the patient.

[According to still] In another [advantageous] embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output CO and actual stroke volume SV from the measured cardiac bioimpedance. [In this way these] These parameters thus are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac electrode and the housing of the pacemaker, when an excitation current proceeds from the electrode tip.

[Brief Description of the Drawings

The invention will now be described more in detail with reference to the enclosed drawings on which figure 1 is a block diagram of an embodiment

chosen as an example of the pacemaker according to the invention and figure 2 illustrates the principle of bioimpedance measurements between the tip of an intracardial electrode and the metal housing of the pacemaker.

Description of a Preferred Embodiment]

DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic block diagram of a rate adaptive pacemaker constructed and operating in accordance with the principles of the present invention.

Figure 2 illustrates the principle of bioimpedance measurements between the tip of an intracardial electrode and the metallic housing of the pacemaker, these measurements being used in the rate adaptive pacemaker of Figure 1.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

To avoid [that] the current cardiac output CO

$$CO = SV \times HR \quad (5)$$

becomes lower than the rest state cardiac output CO_{rest} the pacing rate must be above a lower pacing rate limit given by

$$\text{lower pacing rate limit} = (_{Corest})/(SV) \quad (6)$$

and since

$$CO_{rest} = HR_{rest} \times {}_{Svrest} \quad (7)$$

$$\text{lower pacing rate limit} = (HR_{rest}) \times ({}_{Svrest}/SV) \quad (8)$$

In addition [thereto] the maximum value of the stroke volume must be limited, i.e.

$$SV < L \times SV_{rest} \quad (9)$$

Thus, the following two conditions must be fulfilled simultaneously for insuring a physiologically well founded heart work management at low work loads.

$$\text{Pacing rate limit} > (HR_{rest}) \times (SV_{rest}/SV) \quad (10)$$

$$SV/SV_{rest} < L \quad (11)$$

where L is a constant typically equal to a value of 1.2 to 1.5, depending on the health of the patient's myocardium.

Thus the lower pacing rate limit is continuously automatically calculated from the measured actual stroke volume SV and known values of SV_{rest}, HR_{rest} and the constant L. The actual stroke volume can be determined from e.g. bioimpedance measurements as will be described below.

Figure 1 is a block diagram of an embodiment of the pacemaker according to the invention [comprising] having a bioimpedance measurement unit 2 for measuring the time variation of the electric intracardiac bioimpedance $Z_e(t)$. This type of [measurements] measurement is well-known, see e.g. "Design of Cardiac Pacemakers", edited by John G. Webster, IEEE Press, 1995, pp. 380-386 and [US-A-] United States Patent Nos. 5,154,171, 5,280,429, 5,282,840 and 5,807,272. Thus the time variation of the intracardiac bioimpedance can be measured between the tip

4 of the intracardiac electrode 6 and the housing 8 of the pacemaker, when an excitation current is fed from the electrode tip 4, as schematically illustrated in [figure] Figure 2. Thus a standard pacing lead can be used for this measurement.

From the measured time variations AZc(t) the stroke volume SV needed for calculating the lower pacing rate limit according to equation (8) above, or for checking the inequalities (10) or (11), are determined in a computing [means] unit 10, see [figure] Figure 1.

The calculated lower limit value is supplied to a lower limit 30 setting [means] unit 12 of a pacing rate limiter 14.

A pacing rate controller 16 is also provided for controlling the pacing rate of the pacer or pulse generator 18 in response to the patient's demands. In a limiting unit 20 of the limiter 14 the demanded pacing rate is compared to the set lower limit pacing rate and the actual pacing rate is limited to the set lower limit value if the demanded pacing rate reaches this limit value. Thus in the pacemaker according to the invention a lower limit value for the pacing rate is continuously automatically determined and it is continuously automatically verified that the actual pacing rate does not exceed the present lower limit value.

Alternatively, the pacemaker can be modified to continuously monitor that the inequalities (10) or (11) above are satisfied.

Above bioimpedance measurements are described for determining the stroke volume SV. This parameter can, however, also be determined by

other techniques, like by ECG measurements, by ultrasound technique, by radiometric and optical techniques etc. Generally all dynamic distance and/or capacity measuring methods are applicable.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.